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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,514	02/05/2002	Jeffrey Roger Granett	P31824C1	1080

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EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 10/068,514	Applicant(s) GRANETT ET AL.	
	Examin r Donna A. Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14 and 23-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,14 and 23-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 12, 14 and 23-54 are pending in this application.

Response to Arguments

The rejection made in paper number 6 over Antonucci et al. U.S. Patent No. 5,972,944 under 35 U.S.C. §102(e) is maintained and is hereby repeated.

Applicant asserts that Antonucci fails to teach each and every element of the present claims and therefore does not anticipate the present claims. Applicants argument is directed to the process of admixing the compound (I) in a pharmaceutically acceptable form and a carrier and admixing the first composition with a second pharmaceutically acceptable carrier to produce an administrable dosage form of from 1 to 8 mg.

In response, Antonucci et al. teach preparation of the formulation of the active compound with encapsulating material as a carrier providing a capsule in which the active component with (or without) other carriers, is *surrounded* by a carrier. Thus, there is the first formulation of the active compound in a carrier, and is then surrounded by a carrier.

Further, the tableting technique claimed in the instant application is revealed in the instant specification as a well-known "wet granulation" process (see Remington's Pharmaceutical Sciences (U)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14 and 23-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antonucci et al. U.S. 5,972,944 in view of Remington's Pharmaceutical Sciences (U) and The Physician's Desk Reference (V).

The claims are drawn to a process for preparing a pharmaceutical composition of 5-[4-[2-(N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (rosiglitazone or "compound I) comprising preparing a first composition comprising Compound I in a carrier and admixing the first composition with a second carrier thus formulating a composition in unit dose form comprising 2 to 8 mg of compound I.

Antonucci et al. teach method of preparation of the formulation of the active compound which includes 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]2,4thiazolidine or rosiglitazone (column 17, lines 14-15) with encapsulating material as a carrier providing a capsule in which the active component with (or without) other carriers, is *surrounded* by a carrier. Thus, there is the first formulation of the active compound in a carrier, and is then surrounded by a further carrier column 18, lines 58-62). In any event, the two step technique that applicant is claiming is well known to one of ordinary skill in the art as the "wet granulation" technique as recited in Remington's Pharmaceutical Sciences (pages 1583-1586) wherein the active ingredient, diluent and disintegrator are mixed or blended well (page 1583, column 2, 2nd paragraph), then solutions of the binding agent are added to the mixed powders with stirring to form granules (page 1584, column 2, 1st full paragraph). After the granulation mass is dry, a lubricant is added (page 1586, column 2, 2nd paragraph). It is noted that the instant specification reveals that it is indeed the wet granulation technique that is used for the two-part preparation (page 6, lines 8-14).

The maleate salt of instant claims 31 and 50 is clearly recited in column 17, line 46.

Antonucci et al. does not teach the specific amount of the preparation which is firstly encapsulated with a carrier before adding a second carrier. Antonucci et al. teach the powders and tablets of the reference to be preferably from 5% to about 70% of the active compound. The criticality of the quantity of active agent in the first composition has not been demonstrated. One would have been motivated to employ from 2% to 50% of active in the first compound motivated by the recitation of Remington's Pharmaceutical Sciences that recites that the first step to mixing a wet granulation formulation is to add active ingredient, diluent and disintegrator (page 1583, column 2, 2nd paragraph).

Antonucci et al. does not teach the specific dose of from 2 to 8 mg or 1 to 8 mg. It does, however teach the dosage of from 0.5 to 100 mg. It would have been obvious to one of ordinary skill in the art to prepare a dosage of rosiglitazone of from 1 to 8 mg. One would have been motivated to produce dosage forms of rosiglitazone of from 1 to 8 mg since the only FDA approved usage of the composition is for treatment of diabetes and the recommended dosage is from 2 to 8 mg up to two times a day with specific dosage titrations higher or lower (see Physicians Desk Reference (V) page 2984).

Regarding the solvate in the hydrate form of instant claims 32-34, Antonucci et al. recite that compounds of the present invention can exist in unsolvated forms as well as solvated forms, including hydrated forms. In general, the solvated forms, including hydrated forms are equivalent to unsolvated forms and are intended to be encompassed within the scope of the present invention (column 18, lines 14-19).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Frederick Krass
Primary Examiner
Art Unit 1614

dj
March 13, 2003